REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendment and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 3-5, 8, 10-15 and 17-32 are pending. Claims 1, 4, 5, 8, 11-15, 17-24, 26-29, 21 and 32 are amended without prejudice. Support for the amended recitations in the claims is found throughout the specification.

It is submitted that these claims, as originally presented, were patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments and remarks presented herein are not made for the purpose of patentability within the meaning of 35 U.S.C. sections 101, 102, 103 or 112. Rather, the amendments and remarks are submitted simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTIONS

Claims 1, 4, 5, 8, 10-15, 17-24 and 26-32 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. The Examiner alleges that the phrase "at least one active ingredient solution or dispersion which is not miscible in water" recited in claim 1 is unclear. Applicants disagree.

Applicants respectfully point out that page 6, lines 1 and 2, of the specification recites that the active ingredient is not miscible with water. This also applies to the drug solution/drug dispersion, as seen on page 7, lines 12-13. Thus, claim 1 is manifestly clear.

Reconsideration and withdrawal of the Section 112, second paragraph, rejections are respectfully requested.

III. 35 U.S.C. §§102/103 REJECTIONS

Claims 1, 5, 8, 10-15, 17-22, 24, 26, and 30-31 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Enscore et al. WO 98/00118; and claims 1, 5, 8, 10-12, 17-20, 24, 26-28, and 30-31 were rejected under 35 U.S.C.§102(b) as allegedly being anticipated by Tucker et al. WO 89/07959. Claim 23 was rejected under 35 U.S.C §103(a) as being allegedly unpatentable over by Enscore et al. WO 98/00118; claims 15 and 29 were rejected under 35 U.S.C.§103(a) as allegedly being unpatentable over WO 89/07959; claim 4 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 89/07959 or Enscore et al. (WO 98/00118) in view of Takayasu et al. (U.S.5,478,568); and claim 32 was rejected under 35 U.S.C.§ 103(a) as allegedly being unpatentable over WO 89/07959 in view of Place et al. (U.S.5,242,391). These rejections will be collectively addressed and are respectfully traversed. None of the cited documents teach, suggest, enable or motivate a skilled artisan to practice the instant invention.

The instant invention is directed to drug delivery in a surge. Enscore does not teach, enable or suggest such an invention. More specifically, Enscore relates to a transdermal device having a copolymer membrane. (*See* page 13, lines 3-10). A skilled artisan would readily understand that a membrane does not lead to surge release of a active ingredient. Instead, a membrane releases an active ingredient in a rate-controlled manner. Enscore concedes as much on page 13, line 3, by use of the term "rate-controlling membrane."

Tucker is equally defective. Like Enscore, Tucker also uses a membrane and states on page 6, lines 4-7 that rate delivery is "substantially constant over a greater proportion of the total dose contained in the reservoir." Tucker, in other words, relates to controlled release of the active ingredient, not surge release as instantly claimed.

Applicants take exception to the allegation in the Office Action that inherency is in play. More specifically, the Examiner alleges that the Tucker device inherently releases the active ingredient in a surge simply because the Tucker device and the instant invention presumably have the same composition. First, the Tucker device and the instant invention are not the same. As explained above, the Tucker device uses a rate-controlling membrane, whereas the instant invention does not.

Second, it is impermissible to apply the inherency doctrine absent a disclosure or suggestion in Tucker of the properties of Applicants' invention, i.e., surge delivery. The Examiner is respectfully reminded that a prior art document must disclose or suggest the properties of the claimed invention for inherency to attach. According to *In re Rijckaert*, 9 F.3d 1531, 1957 (Fed. Cir. 1993), "such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection." The Federal Circuit is clear that " 'inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency].' " *Continental Can Company v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), *citing to In re Oelrich*, 666 F.2d 578, 581-582 (C.C.P.A. 1981). Indeed, "before a reference can be found to disclose a feature by virtue of its inherency, one of ordinary skill in the art viewing the reference must understand that the unmentioned feature at issue is *necessarily* present in the reference." *SGS-Thomson Microelectronics, Inc. v. International Rectifier Corporation*, 31 F.3d 1177 (Fed. Cir. 1994) (emphasis in original). Consequently, inherency is inapplicable as a basis for unpatentability.

The combination of Enscore and Takayasu would also not lead a skilled artisan to practice the instantly claimed invention. Instead, a combination of these documents would result in a transdermal device having a rate-controlling membrane.

Further, such a combination would also require water. More specifically, Takayasu notes in column 2, lines 58-62, that "the water-soluble polymer (a) in the transdermal composition according to the present invention promotes absorption of the active ingredient, butyrophenone drug (e), by holding a lot of water and enhancing the hydration of the skin." This is patentably distinguishable from the instant invention, wherein moisture of the skin enters Applicants' transdermal system and leads to a complete breakdown and release of the active ingredient in a surge. (*See*, page 4, lines 28-31, page 5, paragraphs 6 and 7, and page 7). The transdermal system of Takayasu, on the other hand, contains water as a structural element so that the structure of its device cannot be subject to breakdown.

The combination of Tucker and Takayasu, as well as the combination of Tucker and Place, are similarly defective. As explained above, Tucker uses a rate-controlling membrane which prevents drug delivery in a surge. Neither Takayasu nor Place remedy the inherent deficiencies in Tucker. Takayasu, as explained above, requires water to prevent the device from breakdown. Place, in turn, is relied upon by the Examiner solely to meet the present invention's active ingredient recitation. However, since dependent claim 32 depends from claim 1, the rejection based on the additional reference to Place should be withdrawn in view of the above remarks.

Further, it is well-settled that "obvious to try" is <u>not</u> the standard upon which an obviousness rejection should be based. *See In re Fine.* And as "obvious to try" would be the only standard that would lend the Section 103 rejection any viability, the rejection must fail as a matter of law. Therefore, applying the law to the instant facts, the rejections are fatally defective and should be removed.

Consequently, reconsideration and withdrawal of the Sections 102 and 103 rejection are believed to be in order and such actions are respectfully requested.

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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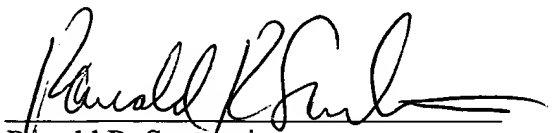
By: 

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